AUG 1 1 2004

K041780

SUMMARY OF SAFETY AND EFFECTIVENESS (21CFR 807.92)

1. SUBMITTER:

Nancy Butcher
Medical Imaging Solutions, Inc.
400 Central Avenue
Jefferson, LA 70121

2. DEVICE NAME:

Trade/Proprietary Name: NewBrid

3. DEVICE CLASSIFICATION:

21 CFR 892.1600 - Angiographic x-ray system
21 CFR 892.1650 - Image-intensified fluoroscopic x-ray system
Class II (90 IZI and MQB)

4. DEVICE DESCRIPTION AND INTENDED USE:

The system is intended for use in cardiovascular x-ray imaging applications, including diagnostic and interventional procedures.
The MIS NewBrid System is the result of integrating new and or refurbished/rebuilt positioners, components and digital imaging systems that are previously cleared by the FDA. Some of the new components will change the original manufacturers specifications and functionality. For example, MIS could remove the original manufacturers Image Intensifier-based imaging chain and replace it with new components or with a solid-state flat panel detector. MIS will integrate its own system interface rack for system control. The image acquisition package will be replaced with a system purchased from an OEM that has 510[k] approval. The pivoting base will allow for an extend area of patient imaging coverage.

5. INDICATION FOR USE:

The system is intended for use in cardiovascular x-ray imaging applications, including diagnostic and interventional procedures (such as PTCA, stent placement, atherectomies), pacemaker implantations, and electrophysiology. It may also be used for other imaging applications at the physician's discretion.

7. PREDICATE DEVICE(s):

The MIS Newbrid System is substantially equivalent, in terms of its intended use in:
Philips Integris Series [K984545]
GE Medical System Advantx LCV+ [K960575]
GE Medical System Innova [K023178]

8. SAFETY INFORMATION:

The finished device and its peripherals will comply with applicable requirements of the Underwriter Laboratories Standard for Safety UL 2601, Title 21 CFR part 1020, and comply with the ACR/NEMA DICOM digital imaging communications standard.

Only trained professionals will utilize the MIS NewBrid system. Trained professionals allow sufficient review to afford identification and intervention in the event of a malfunction.

Medical Imaging Solutions will consider using only components from angiographic and fluoroscopic x-ray systems that were previously cleared by the FDA for their refurbishing and rebuilding process. By retaining criteria for the substitution of components, any concerns about safety or efficacy and substantial equivalence can be satisfactorily met by a determination that the component substitution will not significantly change in the system. This is consistent with the existing Agency guidance.

9. CONCLUSION:

Medical Imaging Solutions concludes that the subject device is safe and effective including the component and accessory devices. The system does not introduce any new indications for use, nor does the use of the device result in any new potential hazard. Medical Imaging Solutions believes sufficient information is included to reach a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Nancy Butcher
Regulatory Affairs
Medical Imaging Solutions, Inc.
800 Central Ave.
JEFFERSON LA 70121

JUL 30 2012

Re: K041780
Trade/Device Name: NewBird Angiographic and Fluoroscopic X-ray Systems
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB and JAA
Dated: July 1, 2004
Received: July 1, 2004

Dear Ms. Butcher:

This letter corrects our substantially equivalent letter of August 11, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): N/A

Device Name: NewBrid Angiographic and Fluoroscopic X-ray Systems

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

Over the Counter Use _____

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K044780